

Application No. 09/911,047
Amendment Dated September 12, 2005
Reply to Office Action of May 10, 2005

REMARKS/ARGUMENTS

By this Amendment, claim 1 and 27 are amended, and claims 34-37 are added.

Claims 1-4, 6-9 and 12-37 are pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Support for the amendments is apparent in the original disclosure. In particular, clause (f) of claim 1 and clause (e) of claim 27 find support in the specification at page 9, lines 27-29. New claims 34 and 36 find support in the Examples, which apply electric voltage for 15 seconds (Example 1; page 16, lines 16-18) or less (11 seconds in Example 4; page 23, lines 24-26). New claims 35 and 37 find support in the specification at page 7, lines 5-8.

Rejections under 35 U.S.C. § 112

Claims 1-4, 6-9 and 12-33 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

a) **Claim 1**

Claim 1 specifies that "said probe hybridizes specifically with said target to form a homologous duplex, a homologous triplex, a homologous quadruplex, a Watson-Crick triplex or a Watson-Crick quadruplex." The Office Action asserts that the complexes of claim 1 are defined in a manner inconsistent with the incorporated by reference application (U.S. App. Serial No. 09/909,496; Att. Docket No. E1047/20057), and therefore the prior amendment of claim 1

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lacked support in the '496 application and in the present application.

Applicants respectfully submit that this rejection is based on an improper interpretation of the claim language. In essence, the Office Action has interpreted "homologous triplex" and "homologous quadruplex" in present claim 1 as meaning a triplex or quadruplex consisting of only like-to-like association of bases among all 3 or 4 strands of the complex. There is no basis in the specification, the documents incorporated by reference, or the prior art for limiting the present claims to such an interpretation.

The present specification references earlier patent applications for details regarding triplex and quadruplex complexes:

Preferred embodiments of the invention specifically detect triplex and/or quadruplex hybridization between the probe and the double-stranded target, thus obviating the need to denature the target. Triplex and quadruplex formation and/or stabilization is enhanced by the presence of an intercalating agent in the sample being tested. See, e.g., U.S. Patent Application No. 09/885,731, filed June 20, 2001, and the U.S. Patent Application having the Attorney Docket No. E1047/20057, entitled "PARALLEL OR ANTIPARALLEL, HOMOLOGOUS OR COMPLEMENTARY BINDING OF NUCLEIC ACIDS OR ANALOGUES THEREOF TO FORM DUPLEX, TRIPLEX OR QUADRUPLEX COMPLEXES", filed July 20, 2001.

and teaches nothing about triplexes or quadruplexes inconsistent with the cross-referenced applications. Therefore, the interpretation to be applied should be that suggested by the cross-referenced applications. The Office Action correctly understood from the '496 application that homologous complexes include like-to-like bonding as well as Watson-Crick bonding.

It is clear from the '496 application that triplexes and quadruplexes are named by reference to the binding motifs of the additional strand(s) added to the core duplex. See, e.g.,

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Example 8 of the '496 application, which shows a "homologous quadruplex" consisting of a Watson-Crick duplex probe and a Watson-Crick duplex target, wherein the probe and target are associated with one another by homologous binding rules.

This naming convention is consistent with such conventions used in the prior art. For example, "Hoogsteen triplexes" contain a Watson-Crick duplex and a third strand bonded to the W-C duplex via Hoogsteen bonds.

Thus, there is nothing inconsistent in reciting "said probe biopolymer sequence and said target biopolymer sequence contain nucleobases and said probe hybridizes specifically with said target to form a homologous duplex, a homologous triplex, a homologous quadruplex, a Watson-Crick triplex or a Watson-Crick quadruplex."

b) Claims 17-19

The recitation in claims 17-19 of the expression "substantially free of Hoogsteen bonding" finds support in the '496 application at page 10, lines 8-10.

c) Claim 19

The recitation in claim 19 of the expression "free of G-G quartets" finds support in the '496 application at page 10, lines 8-10.

d) Claims 27-29 and 33

Application of the first/second stimulus "directly" to the sample finds support in the present specification at, e.g., page 16, lines 16-20, which read as follows:

Samples were placed into a 3 mm quartz cuvette and were subjected to 1 or 5 volts DC (V) electrification for 15 seconds. The amperometric assay

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consisted of the monitoring of current while the voltage was being applied to the solution.

A person of ordinary skill in the art would recognize that applicants were in possession of an embodiment comprising "directly" applying the stimulus to the sample, based on this example in which DC voltage (i.e., the stimulus) was applied to the solution (i.e., the sample) to electrify the sample.

Accordingly, reconsideration and withdrawal of the written description rejection are respectfully requested.

Claims 1-4, 6-9 and 12-33 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

(a) Claim 1

As noted above, a homologous triplex contains a core Watson-Crick duplex to which a third strand is associated by like-to-like association between opposing bases. Likewise a homologous quadruplex contains two core Watson-Crick duplexes, wherein at least one strand of one duplex is associated with at least one strand of the other duplex by a homologous binding motif.

The alleged use of the term "homoduplex" by others should not foreclose applicants' use of the expression "homologous duplex". Applicants are entitled to be their own lexicographers, and have chosen a term that is unique and clearly defined in the specification, including the information incorporated by reference from their earlier applications. See MPEP 2173.05.

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b) Claims 17-19

The expression "substantially free of Hoogsteen bonding" further limits the probe-target bonding of claim 1, because the transitional phrase "comprising" leaves claim 1 open to additional unspecified features.

Accordingly, reconsideration and withdrawal of the indefiniteness rejection are respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 1-4, 6, 8, 12-13, 15, 17-18, 20-22, 24-25 and 27-33 stand rejected under 35 U.S.C. § 102(a) and (e) as allegedly being anticipated by Cummins et al. (U.S. Patent No. 5,874,213). This rejection is respectfully traversed.

Cummins et al. fails to identically disclose each and every limitation of the claimed invention. Cummins et al. relates to capillary electrophoretic detection of nucleic acids (see Title, Abstract, etc.). As noted in Cummins et al. at column 9, lines 58-60, "separation of hybridized moieties from other components of a mixture or sample is achieved by capillary electrophoresis."

Thus, Cummins et al. fails to meet the limitation of base claims 1 and 27 that the method is conducted without separating probe-target complexes from free probes and targets.

Accordingly, reconsideration and withdrawal of the anticipation rejection over Cummins et al. are respectfully requested.

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Claims 7, 9 and 23 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cummins et al. in view of Meade et al. (U.S. Patent No. 6,071,699). This rejection is respectfully traversed.

The Office Action fails to set forth a *prima facie* case of obviousness with respect to this rejection. No attempt is made to show any motivation to modify the teachings of Cummins et al. with the teachings of Meade et al. to reach the invention of claims 7, 9 and 23 with a reasonable expectation of success. See MPEP 2143.

In any event, Cummins et al. could not be modified to exclude a separation step as separation is the very essence of the reference. A person of ordinary skill in the art would not be reasonably motivated to modify an electrophoretic assay reference to eliminate electrophoresis.

Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 7, 9 and 23 are respectfully requested.

Claims 14, 16, 19 and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cummins et al. in view of Meade et al. This rejection is respectfully traversed.

Regardless of whether Meade et al. teaches the additional features of claims 14, 16, 19 and 26, the proposed combination of reference teachings still fails to meet all the limitations of the claimed invention. As noted above, a person of ordinary skill in the art would not be reasonably motivated to modify an electrophoretic assay reference to eliminate electrophoresis.

Accordingly, reconsideration and withdrawal of the obviousness rejection of claims 14, 16, 19 and 26 are respectfully requested.

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New claims 34-37 further distinguish over the applied art, by reciting additional features of the electronic stimuli that are not disclosed or suggested by the art.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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